UNITED STATES PATENT AND TRADEMARK OFFICE

UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND
DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

September 2, 2005

IVOR M. HUGHES, BARRISTER & SOLICITOR,
PATENT & TRADEMARK AGENTS
175 COMMERCE VALLEY DRIVE WEST
SUITE 200
THORNHILL, ON L3T 7P6
CA

Dear Sir/Madam,

Your refund request for 10020882 in the amount of $550.00 has been denied .

We do not refund for claims that are withdrawn because they can be reinstated. If they are cancelled then a refund is due.

Sincerely,

ELEANOR KURTZ
Technical Center Others
703 308-9010 x177

Ivor M. Hughes
Barrister & Solicitor
Patent & Trade Mark Agents
Canada, United States

Barristers & Solicitors
Ivor M. Hughes
Rick Tuzi

Patent Agents
Neil H. Hughes, P.Eng.
Marcelo K. Sarkis, P.Eng.
Wm. Kitt Sinden
Samuel T. Tekie, P.Eng.

Our Ref.: PT-1949001

June 30, 2005

VIA FACSIMILE: 703-308-5077

Director of the United States Patent and Trademark Office
Attention: Deposit Accounts
One Crystal Park
2011 Crystal Drive, Suite 307
Arlington, Virginia, 22202

Dear Sir:

Re: Response to Examination Report
Application Serial No. 10/020,882 filed on December 19, 2001
of Dialysis Solutions Inc.
for STERILE LOW BICARBONATE DIALYSIS CONCENTRATE
Group Art Unit: 1616
Examiner: John D. Pak
Deposit Account No. 08-3255
Customer No. 23607

Upon reviewing our deposit account 08-3255, we note that $150.00 in excess claim fees and $400.00 in independent claim fees was withdrawn from our deposit account May 27, 2005, in response to the official action dated December 28, 2004.

According to your accounting records, there are presently 7 independent claims and 16 dependent claims. Upon reviewing the response dated May 18, 2005, we note that claims 2-8, 11-13 and 15-16 are withdrawn from this application. Accordingly, there are only 5 independent claims and 6 dependent claims and not 7 independent claim and 16 dependent claims as indicated on the worksheet of May 19, 2005.

Since both the total number of claims and independent claims have been reduced from the Voluntary Amendment filed July 7, 2003, we require that the $550.00 be reversed and returned to our deposit account. We enclose a copy of our response dated May 18,

2005 along with revised work sheets. We also enclose a copy of our deposit account statement for May 2005, showing the transaction that occurred in error.

If this is incorrect or any questions arise, please contact the undersigned.

Respectfully submitted,

Neil H. Hughes, P.Eng.
Agent for Applicant
Registration No. 33,636

NHH:md
Enclosures

cc: Examiner John D. Pak (via facsimile, 571 272 1600)
bcc: Rose Mann

CLAIMS ONLY

SERIAL NO. 10/20182

FILING DATE

APPLICANT(S)

CLAIMS

	AS FILED		AFTER 1st AMENDMENT 5/14/05		AFTER 2nd AMENDMENT	
	IND.	DEP.	IND.	DEP.	IND.	DEP.
1	I		/			
2		/		X		
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TOTAL IND.	2		5 / 7			
TOTAL DEP.	10		16	6		
TOTAL CLAIMS	12		23	11		

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	IND.	DEP.	IND.	DEP.	IND.	DEP.
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TOTAL IND.						
TOTAL DEP.						
TOTAL CLAIMS						

* MAY BE USED FOR ADDITIONAL CLAIMS OR AMENDMENTS

FORM PTO-2022 (1-68)

U.S. DEPARTMENT OF COMMERCE
Patent and Trademark Office

*U.S. Government Printing Office: [illegible]

PATENT APPLICATION FEE DETERMINATION RECORD
Effective October 1, 2001

Application or Docket Number: 10/626,882

CLAIMS AS FILED - PART I

	(Column 1)	(Column 2)
TOTAL CLAIMS	12	
FOR	NUMBER FILED	NUMBER EXTRA
TOTAL CHARGEABLE CLAIMS	12 minus 20=	* —
INDEPENDENT CLAIMS	2 * minus 3 =	* —
MULTIPLE DEPENDENT CLAIM PRESENT		☐

* If the difference in column 1 is less than zero, enter "0" in column 2

SMALL ENTITY TYPE ☐			OR	OTHER THAN SMALL ENTITY	
RATE	FEE			RATE	FEE
BASIC FEE	370.00		OR	BASIC FEE	740.00
X$ 9=			OR	X$18=	
X42=			OR	X84=	
+140=			OR	+280=	
TOTAL			OR	TOTAL	740

CLAIMS AS AMENDED - PART II

7/7/03

AMENDMENT A

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	* 17	Minus	** 20	=
Independent	* 5	Minus	*** 3	= 2
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

SMALL ENTITY			OR	OTHER THAN SMALL ENTITY	
RATE	ADDITIONAL FEE			RATE	ADDITIONAL FEE
X$ 9=			OR	X$18=	
X42=			OR	X84=	168
+140=			OR	+280=	
TOTAL ADDIT. FEE			OR	TOTAL ADDIT. FEE	168

5/19/05

AMENDMENT B

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	* 25 11	Minus	** 20	= 30
Independent	* 15	Minus	*** 5	= 20
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

SMALL ENTITY			OR	OTHER THAN SMALL ENTITY	
RATE	ADDITIONAL FEE			RATE	ADDITIONAL FEE
X$ 9=			OR	X$18= 50	150
X42=			OR	X84= 200	400
+140=			OR	+280=	
TOTAL ADDIT. FEE			OR	TOTAL ADDIT. FEE	550

AMENDMENT C

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

SMALL ENTITY			OR	OTHER THAN SMALL ENTITY	
RATE	ADDITIONAL FEE			RATE	ADDITIONAL FEE
X$ 9=			OR	X$18=	
X42=			OR	X84=	
+140=			OR	+280=	
TOTAL ADDIT. FEE			OR	TOTAL ADDIT. FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20."
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3."
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

United States Patent and Trademark Office

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Deposit Account Statement

Requested Statement Month:	May 2005
Deposit Account Number:	083255
Name:	IVOR M. HUGHES, BARRISTER & SOLICITOR
Attention:	ESTE HUGHES
Address:	175 COMMERCE VALLEY DR WEST
City:	THORNHILL
State:	
Zip:	L3T 7P6
Country:	CANADA

DATE	SEQ	POSTING REF TXT	ATTORNEY DOCKET NBR	FEE CODE	AMT	BAL
05/03	18	10139347	572659	1401	✓$500.00	$3,709.09
05/03	19	10139347	572659	1253	✓$1,020.00	$2,689.09
05/04	15	PAYMENT		9203	✓-$2,000.00	$4,689.09
05/24	8	10505092		9204	-$198.00	$4,887.09
05/27	1	10020882	EEC-10002/38	1202	$150.00	$4,737.09
05/27	2	10020882	EEC-10002/38	1201	$400.00	$4,337.09

excess claims PT1949 (150.00) — 1 independent claim (400.00)

START BALANCE	SUM OF CHARGES	SUM OF REPLENISH	END BALANCE
$4,209.09	$2,070.00	$2,198.00	$4,337.09

4337.09
OCD — 715.00
3622.09
Reverse credit — 198.00
3424.09
PT2093 — 180.
3244.09

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IN THE UNITED STATES PATENT OFFICE

COPY

Our Ref.: PT-1949001
CUSTOMER NO. 23607

Application Serial No. 10/020,882

Filing Date: December 19, 2001

Applicants Dialysis Solutions Inc.

Agent: Neil H. Hughes, P.Eng.
c/o Ivor M. Hughes
Barrister & Solicitor
Patent & Trademark Agents
Suite 200
175 Commerce Valley Dr. W.
Thornhill, Ontario
Canada ,L3T 7P6

Title: STERILE LOW BICARBONATE DIALYSIS CONCENTRATE

Inventor: Sheldon Tobe

Examiner: John D. Pak

Group Art Unit: 1616

Due Date: May 28, 2005

RESPONSE TO OFFICIAL ACTION
OF DECEMBER 28, 2004
AMENDMENTS AND REMARKS

May 18, 2005

VIA COURIER

United States Patent and Trademark Office
Customer Service Window
Randolph Building
401 Dulany Street
Alexandria, Virginia
22314

Dear Sir:

INTRODUCTORY COMMENTS

In response to the outstanding Official Action dated December 28, 2004 and due for response March 28, 2005, Applicant encloses a Request for a two month extension of time with the fee for a large entity of $450.00 U.S. funds making this response due May 28, 2005. Applicant also include herewith a Supplementary Information Disclosure Statement long with the necessary fee of $180.00. If there is any deficiency or surplusage of the fees enclosed for the Extension of Time (fee), please obtain any such deficiency or credit the surplusage to Deposit Account 08-3255 and advise Applicants' Agent.

In response to the outstanding Official Action of December 28, 2004, please amend the above-identified application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 3 of this paper.

Remarks/Arguments begin on page 7 of this paper.

Attachments: Request for a 2 Month Extension of Time;
Cheque in the amount of $630.00 USD;
Printout of Trade Mark Registration of NORMOCARB;

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Claim 1 (currently amended) A sterile calcium free low bicarbonate dialysis concentrate composition for use in the preparation of a dialysis solution comprising sodium chloride (NaCl), ~~90.72±9.0 g/l~~ magnesium chloride (MgCl2), ~~2.05±0.2 g/l~~, and a concentration of bicarbonate sodium bicarbonate (NaHCO3) ~~28.35±2.8 g/l~~ sufficiently low so as to allow preparation of a sterile dialysis solution having a bicarbonate concentrate of 5-30 mmol/l.

Claim 2 (withdrawn) A kit for preparing a dialysis solution comprising the sterile dialysis concentrate composition of claim 1 and optionally instructions for its use.

Claim 3 (withdrawn) The kit of claim 2 further comprising sterile water sufficient to dilute the concentrate to a solution comprising Na 140±14 mmol/l, Mg 0.75±0.07 mmol/l, Cl 116.5 ± 11 mmol/l, and HCO3 25.0 ± 2.5 mmol/l.

Claim 4 (withdrawn) A method of preparing a sterile dialysis solution comprising diluting a sterile, dialysis concentrate composition of claim 1 in a sufficient amount of sterile water to prepare a dialysis solution comprising Na 140±14 mmol/l, Mg 0.75±0.07 mmol/l, Cl 116.5 ± 11 mmol/l, and HCO3 25.0 ± 2.5 mmol/l.

Claim 5 (withdrawn) A method for providing continuous renal replacement therapy to a patient comprising administering a sterile dialysis solution prepared according to the method of claim 4 in conjunction with a regional citrate anti-coagulant solution to a patient in need thereof.

Claim 6 (withdrawn) A method of preparing a sterile dialysis solution or infusate comprising diluting a sterile, dialysis concentrate composition of claim 1 in a sufficient amount of sterile water to prepare an infusate comprising Na 140±14 mmol/l, Mg 0.75±0.07 mmol/l, Cl 116.5 ± 11 mmol/l, and HCO3 25.0 ± 2.5 mmol/l.

Claim 7 (withdrawn) A method for treating acute renal failure in a critically ill patient without introducing calcium into the blood removed from the patient during dialysis comprising administering a sterile dialysis solution prepared according to the method of claim 6 in conjunction with a regional citrate anti-coagulant solution to a patient in need thereof.

Claim 8 (withdrawn) A method for providing hemofiltration to a patient comprising administering a sterile infusate prepared according to the method of claim 6 in conjunction with a regional citrate anti-coagulant solution to a patient in need thereof.

Claim 9 (original) A sterile dialysis solution comprising the concentrate as claimed in claim 1 and a physiologically acceptable diluent.

Claim 10 (original) A sterile dialysis solution according to claim 9 comprising Na 140±14 mmol/l, Mg 0.75±0.07 mmol/l, Cl 116.5 ± 11 mmol/l, and HCO3 25.0 ± 2.5 mmol/l.

Claim 11 (withdrawn) A method of preparation of a sterile calcium-free bicarbonate concentrate according to claim 1 as an infusate for hemofiltration.

Claim 12 (withdrawn) A method of preparation of a sterile, calcium free bicarbonate concentrate according to claim 1 as a dialysis solution for use in metabolic acidosis.

Claim 13 (withdrawn) A method for correcting bicarbonate levels in a patient during dialysis comprising providing a dialysate mixture having a bicarbonate level sufficiently low so as to minimize the risk of metabolic complication in the patient, preferably between 20-30 mmol/litre, wherein should the patient's bicarbonate level drop below the preferred level, bicarbonate diffuses from the dialysate across the semipermable membrane to the patient to correct the problem, and wherein if there is an excess of bicarbonate in the blood of the patient then bicarbonate diffuses from the blood to the dialysate to correct the problem.

Claim 14 (previously presented) A sterile calcium free low bicarbonate concentrate containing magnesium, sodium, chloride, and a concentration of bicarbonate sufficiently low so as to minimize the risk of metabolic complications in a patient, and for continuous renal replacement therapies such as dialysis and hemofiltration, wherein the bicarbonate level in the resulting dialysis solution is within the range of about 5-30 mmol/litre.

Claim 15 (withdrawn) A method for treating acute renal failure in a critically ill patient comprising dialyzing blood from the patient, without introducing calcium into the blood removed from the patient during dialysis, by using a sterile dialysis solution having a bicarbonate concentration within the range of about 5-30 mmol/litre.

Claim 16 (withdrawn) The use of claim 15 wherein the solution further comprises at least one of potassium, glucose, and ketones such as b hydroxy-butyrate.

Claim 17 (previously presented) A sterile dialysis concentrate, for use in the preparation of a dialysis solution, having a bicarbonate level sufficiently low so as to

minimize the risk of metabolic complications in a patient and comprising sodium chloride, magnesium chloride, and sodium bicarbonate at a concentration in the dialysis solution within the range of about 5-30 mmol/litre.

Claim 18 (new) A calcium free low bicarbonate sterile dialysis concentrate composition for use in the preparation of a sterile dialysis solution comprising a concentration of sodium bicarbonate ($NaHCO_3$) sufficiently low so as to allow preparation of a sterile dialysis solution having a bicarbonate concentration of 5-30 mmol/l.

Claim 19 (new) A calcium free low bicarbonate sterile dialysis solution composition comprising sodium bicarbonate ($NaHCO_3$) in the range of 5 to 30 mmol/l.

Claim 20 (new) A composition according to Claim 19 wherein the sodium bicarbonate is in the range of 20-30 mmol/l.

Claim 21 (new) A composition according to Claim 19 wherein the sodium bicarbonate is 25 mmol/l $\pm$ 2.5 mmol/l.

Claim 22 (new) A composition according to Claim 19 further comprising sodium citrate added when the sodium bicarbonate is below 25 mmol/l.

Claim 23 (new) A composition according to Claim 22 wherein the sodium citrate is present in a level up to 20 mmol/l.

REMARKS/ARGUMENTS

Claims 1, 9, 10, 14, and 17, remain in the application. Applicant has further provided new claims 18 to 23 for the Examiner's further consideration. These new claims are composition claims and have full support from the original disclosure. No new subject matter has been added.

The Examiner has rejected Claims 1 and 10 under 35 U.S.C. 112, second paragraph, as purportedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant has therefore amended claim 1 to more specifically focus the invention to a low bicarbonate calcium free composition having a concentration of bicarbonate sufficiently low to allow preparation of a sterile dialysis solution having a bicarbonate level of 5-30 mmol/l. No new matter has been added in making this amendment and the amendment is fully supported from the disclosure and clearly defines the invention in clear and distinguishing language. Full reconsideration is respectfully requested.

Support for these amendments is found in the definition of the Field of Invention, on page 1 of the disclosure as well as at line 25 onwards of page 6, as well as the first paragraph on page 7. Further support is found in the summary of the invention and specifically at page 9, line 13 onwards.

The Examiner has rejected Claims 9 and 10 under 35 U.S.C. 102(e) as being allegedly anticipated by Mahiout (US 6,492,336). The Examiner purports that Mahiout explicitly discloses a peritoneal dialysis solution that contains anions and

cations with respect to Claim 18 of Mahiout in view of Claim 10 of the present invention.

Applicant has taken note of the Examiner's alleged rejection of claims 9 and 10 as being anticipated by Mahiout, et al. (US 6,492,336). Applicant submits that the peritoneal dialysis fluid of Claim 18 of Mahiout depends on Claim 1 which necessarily includes "at least one sugar derivate" as an essential element of that invention. The "at least one sugar derivative" is present for the removal of water and solutes from a patient by peritoneal dialysis (see column 3, lines 40-43). Applicant submits that such "at least one sugar derivative" is not present nor is it intended to be present in its solution/composition. Applicant further submits that the "at least one sugar derivative" is an essential element of Mahiout's invention and thus a person skilled in the art could not conceivably derive a composition not containing this essential element from the teachings of this patent.

Clearly '336 does not teach a calcium free low bicarbonate dialysis concentrate for use in preparation of a dialysis solution. Every one of the Examples 1-16 of '336 include calcium.

The objects and teachings of '336 are clearly not related to the present invention. Elements of '336 may therefore not be extracted from the specification to pick and chose these points to render the present claim set as uninventive. '336 teaches a glucose free hydrogenated oligosaccharide solution having no effect on cell function during peritoneal dialysis. Claim 18 must therefore be read within these limitations. Further, one will note upon review of the examples provided in the '336 Patent, more specifically examples 2, 6, 10, and 14 it is discussed that the amount of bicarbonate is 2.94 g/l which works out to 35 mmol/l. Also, examples 4, 8, 12, and 16 it is discussed that the amount of bicarbonate is 2.52 g/l which works out to 30

mmol/l. Hence, none of the examples in the '336 Patent discuss or even suggest a calcium-free dialysis solution with 30 mmol/l or less of bicarbonate as is now claimed in the present application. In view of the present amendments to the claims it is submitted that the Examiner's rejection has been traversed in that '336 does not teach a calcium free, low bicarbonate dialysis solution. There is no discussion in '336 to even motivate one skilled in the art in that direction. For prior art to anticipate it must include each and every limitation found in the claims. In view of the amendments this clearly is not the case. Nor would the amended claims be obvious from reading the '336 reference since one skilled in the art would not be motivated to arrive at applicants amended claim set. Full reconsideration is requested.

Applicant submits that in light of the above arguments and the amendments to the claim set, the Examiner's rejection is now overcome.

The Examiner has rejected Claims 14 and 17 under 35 U.S.C. 102(b) as being anticipated by Chemical Abstract 124:325351 (hereinafter referred to as CA '351). The Examiner purports that Chemical Abstract 124:325351 explicitly discloses treating advanced renal failure patients with a calcium-free dialysis solution.

Applicant has taken note of the Examiner's rejection for anticipation in light of CA '351, but submits the following as rebuttal.

Claims 14-17 clearly distinguish from the Chemical Abstract reference. The '351 CA reference does not teach low bicarbonate levels but only that of 30 mmol/l. Applicant further submits that the Chemical Abstract only discloses a composition containing sodium 135 mmol/l, potassium 2.5 mmol/l, chloride 108 mmol/l, magnesium 0.75 mmol/l and bicarbonate 30 mmol/l.

As discussed above in relation to the '336 reference, Applicant submits that the essence of the present invention is particularly summarized at page 7, lines 16-30,

> "... Usage of a low bicarbonate dialysate solution of the invention takes into account the bicarbonate derived from citrate, and as a result the total effective bicarbonate concentration is accounted for and effectively controlled. Thus, metabolic complications are effectively minimized. The low bicarbonate sterile solution of the invention typically contains a bicarbonate concentration within the range of 5-30 mmol/l, preferably between 20-30 mmol/l, and more preferably 25 ± 2.5 mmol/l. The solutions with bicarbonate concentrations below 25 mmol/L may have sodium citrate added to them up to 20 mmol/L to act as an anticoagulant. *(emphasis added)*
>
> The benefit of such a low concentration of bicarbonate as 25 mmol/L is that if the patients bicarbonate level drops below this, bicarbonate diffuses from the dialysate across the semipermeable membrane to the patient correcting the problem. If there is an excess of bicarbonate in the blood (metabolic alkalosis) then bicarbonate will diffuse out into the dialysate effluent and be removed returning the patient toward normal."

Applicant submits that CA '351 does not result in a solution containing less than 30 mmol/l of bicarbonate. There is no indication or motivation in the Chemical Abstract of addressing the problem identified in Applicant's disclosure, or any reasoning for the selecting low levels of bicarbonate in a dialysis solution.

Applicant further submits that the invention in CA '351 would not render the present invention obvious to a person skilled, based on his common general knowledge, since it does not teach or even suggest to have a level of bicarbonate below 30 mmol/l, nor motivate one skilled in the art to do so. Applicant was unable to locate a full copy of CA '351 through it's sources and therefore requests same of the Examiner. It is difficult to determine the teachings in full without a complete copy.

The Examiner has rejected Claims 14 and 17 under 35 U.S.C. 103(a) as being unpatentable over Chemical Abstracts 124:332435 in view of Mahiout.

Applicant submits that neither '336 nor CA '351 would lead a person skilled in the art to prepare and use a solution containing less than 30 mmol/l of bicarbonate. There is no teaching in CA '351 or '336 of the problem Applicant is addressing nor the reasoning for the selected low levels of bicarbonate in his dialysis solution.

Applicant further submits that neither CA '351, or '336 would render the present invention obvious to a person skilled in the art, based on his common general knowledge, since it does not teach or even infer a low level of bicarbonate below 30 mmol/l nor motivate one skilled in the art to do so. Considering that neither reference teaches in this direction, how could any combination of these references result in Applicant's amended claim set. Full reconsideration is requested.

The present invention is clearly novel and unobvious in light of U.S. 6,492,336 B1 for the following reasons.

U.S. 6,492,336 claims (in Claim 18) a dialysis fluid according to Claim 1 containing:

> from 125 to 140 mEG/l of sodium;
> from 90 to 125 mEg/l of chloride;
> from 1 to 5 mEg/l of calcium; (emphasis added)
> from 0.2 to 5 mEg/l of magnesium;
> and from 25 to 40 mEg/l of a buffering anion selected from the group consisting of lactate, pyruvate and bicarbonate.

Therefore the composition cannot be considered as "calcium free". Further, no discussion of low bicarbonate levels is taught nor the reasoning for doing so.

Applicant also submits that in the description of U.S. '336 an essential element of the invention is the presence of "at least one sugar derivative" which derivative is described at column 3, lines 43-59 of that patent. Applicant reminds the Examiner that Claim 18 of U.S. '336 necessarily contains this above referred to "at least one sugar derivative" since it depends on Claim 1.

In light of the above arguments and the amended set of claims, Applicant believes the obviousness rejection in light of U.S. '336 and CA '351 has been overcome. Applicant respectfully requests favourable reconsideration on this point.

The Examiner requests from the Applicant a search report or notification of relevant prior art, written opinion or IPER with regard to related applications, WO 2002/049693 and published CA 2,365,787. Applicant submits to the Examiner that the related prior art from all filings is therefore set out in the attached Supplementary Information Disclosure Statement. The Examiner is referred to the first filed Information Disclosure Statement for the remainder of relevant art.

- U.S. Patent No. 4,630,727 to Feriani et al.
- U.S. Patent No. 5,211,643 to Reinhardt et al.
- U.S. Patent No. 5,945,449 to Purcell et al.
- U.S. Patent No. 6,492,336 to A. Mahiout
- DE 41 14 908 A1
- WO 96/01118
- Yatzidis et al., "*Hemodialysis with a New Single Stable Bicarbonate Dialysate*", Nephron, Vol. 64, 1993; 27-31
- F. H. Leenen, et al., "*Hemodynamic Changes During Acetate and Bicarbonate Hemodialysis*", Artificial Organs 8(4), 1984; 411-417
- M. Kaye et al., "*Calcium-free Dialyzate: Development and Applications*", Clinical Nephrology, Vol. 31, No. 3, 1989; 132-138

- M. Kaye and D. Fisher, "*Changes in Intact Parathyroid Hormone Levels During Hemodialysis Following Exposure to Either Differing Dialyzate Calcium Concentrations or Calcium-Free Dialysis with Varying Calcium Infusion Rates*", Clinical Nephrology, Vol. 34, No. 2, 1990; 84-87

- M. Kaye, "*Long-term studies using a calcium-free dialysate*", Clinical Nephrology, Vol. 40, No. 4, 1993; 221-224

- P.Y.W. Tam et al., "*Slow Continuous Hemodialysis for the Management of Complicated Acute Renal Failure in an Intensive Care Unit*", Clinical Nephrology, Vol. 30, No. 2, 1988; 79-85

- E.F.H. Van Bommel et al, "*Acute Dialytic Support for the Critically Ill: Intermittent Hemodialysis Versus Continuous Arteriovenous Hemodiafiltration*", Am. J. Nephrol., Vol. 15, 1995; 192-200

- E.F.H. Van Bommel, "*Are Continuous Therapies Superior to Intermittent Haemodialysis for Acute Renal Failure on the Intensive Care Unit?*", Nephrol Dial. Transplant 1995 Editorial Comments, p. 311-314

- Davenport et al., "*Hyperlactataemia and Metabolic Acidosis During Haemofiltration Using Lactate-Buffered Fluids*", Nephron, Vol. 59, 1991; 461-465

- M. Leblanc et al., "*Bicarbonate Dialysate for Continuous Renal Replacement Therapy in Intensive Care Unit Patients With Acute Renal Failure*", Am. J. Kidney Diseases, Vol. 26, No. 6, 1995; 910-917

- Knaus W.A. et al., "*APACHE II: A Severity of Disease Classification System*", Critical Care Med., Vol. 13, No. 10, 1985; 818-829

- Jordan, D.A. et al., "*Evaluation of Sepsis in a Critically ill Surgical Population*", Critical Care Med., Vol. 15, No. 10, 1987; 897-904.

Lastly, the Examiner believes "NORMOCARB" to be a bicarbonate based dialysate solution but does not yet have additional information on the product. Therefore, Applicant confirms that NORMOCARB is a registered Trade Mark belonging to the assignee of this application. Please refer to the attached printout which indicates that NORMOCARB® is a Registered Trade Mark owned and marketed at present, by the Assignee of this application.

If any questions arise, the Examiner is respectfully requested to contact Neil Hughes or alternatively Charles Pigeon at (905) 771-6414 collect at the Examiner's convenience.

Respectfully submitted,

Neil H. Hughes
Registration No. 33,636
Agent for the Applicant

NHH:md
Enclosures
1) Request for 2 Month Extension of Time
2) Cheque in the amount of $630.00 USD
3) Printout referring to NORMOCARB
4) Information Disclosure Statement

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